**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| GILEAD SCIENCES, INC. and EMORY UNIVERSITY,<br><br>Plaintiffs,<br><br>v.<br><br>AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,<br><br>Defendants. | C.A. No. _____ |

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs"), for their complaint against Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo"), hereby allege as follows:

## Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

## The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. Emory is a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

4. On information and belief, defendant Aurobindo Pharma Ltd. ("Aurobindo Ltd") is an Indian corporation with a principal place of business at Plot No. 2, Maitrivihar, Ameerpet, Hyderabad 500038, Telangana, India.

5. On information and belief, defendant Aurobindo Pharma USA, Inc. ("Aurobindo USA") is a Delaware corporation with a principal place of business at 279 Princeton-Hightstown Rd, East Windsor, New Jersey 08520-1401.

6. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd, and is controlled and/or dominated by Aurobindo Ltd.

7. On information and belief, Aurobindo Ltd and Aurobindo USA regularly transact business within Delaware, including but not limited to, through Aurobindo Ltd's direction of the operations and management of Aurobindo USA, as well as shipping generic drugs to Aurobindo USA from locations outside the United States for marketing, sale, and distribution by Aurobindo USA within the United States generally, and Delaware specifically.

**Jurisdiction and Venue**

8. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21 of the United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

9. On information and belief, this Court has personal jurisdiction over Aurobindo Ltd.

10. On information and belief, this Court has jurisdiction over Aurobindo Ltd because Aurobindo USA is a Delaware corporation and is the subsidiary and agent of Aurobindo Ltd. On information and belief, Aurobindo USA is acting as the agent of Aurobindo Ltd with respect to Abbreviated New Drug Application ("ANDA") No. 21-1640. On information and belief, Aurobindo Ltd and Aurobindo USA are working in concert for purposes of developing, formulating, manufacturing, marketing, selling, and importing drug products throughout the United States, including Delaware, and Delaware would be a destination of Aurobindo's ANDA products.

11. In the alternative, this Court has jurisdiction over Aurobindo Ltd because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Aurobindo Ltd because, *inter alia*, this action arises from actions of Aurobindo Ltd directed toward Delaware, and because Aurobindo Ltd has purposely availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Aurobindo Ltd regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. On information and belief, Aurobindo Ltd derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

12. On information and belief, this Court has personal jurisdiction over Aurobindo USA.

13. On information and belief, Aurobindo USA is a corporation registered with the Delaware Department of State, Division of Corporations, under file number 3769913.

14. On information and belief, Aurobindo USA maintains a registered agent for service of process in Delaware, the Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

15. On information and belief, Aurobindo USA is a generic pharmaceutical company in the business of marketing and distributing generic drug products, and derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in Delaware.

16. On information and belief, Aurobindo USA, itself or through one of its wholly-owned subsidiaries, manufactures pharmaceutical drug products that are sold and used throughout the United States, including in Delaware.

17. On information and belief, residents of Delaware purchase pharmaceutical drug products marketed by Aurobindo USA in Delaware.

18. On information and belief, Aurobindo USA holds a Delaware pharmacy wholesale license (No. A4-0001270) and a Delaware controlled substances distributor/manufacturer license (No. DM-0006550).

19. On information and belief, Aurobindo USA's submission of ANDA No. 21-1640, discussed below, indicates Aurobindo's intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with Gilead's Truvada® product, which is currently being sold throughout the United States, including in Delaware. On information and belief, Aurobindo will sell tablets containing 100 mg/150 mg, 133 mg/200 mg, and 167 mg/250 mg of emtricitabine/tenofovir disoproxil fumarate, respectively, for the use for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, throughout the United States, including in Delaware.

20. On information and belief, Aurobindo has availed itself of this Court's jurisdiction by filing counterclaims in this District, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g.*, *Amgen Inc. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 16-853-MSG (D. Del.); *Allergan Sales LLC v. Aurobindo Pharma Ltd. et al.*, C.A. No. 15-1032 (D. Del.); *Reckitt Benckiser LLC v. Aurobindo Pharma Ltd. et al.*, C.A. No. 14-1203 (D. Del.).

21. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b). Specifically, venue is proper in Delaware because Aurobindo USA is incorporated in Delaware.

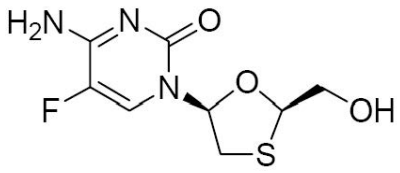
**Background**

22. Gilead is the holder of New Drug Application ("NDA") No. 21-752 which relates to tablets containing emtricitabine and tenofovir disoproxil fumarate. On August 2, 2004, the United States Food and Drug Administration ("FDA") approved the use of the tablets containing 200mg of emtricitabine and 300mg of tenofovir disoproxil fumarate for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Truvada®. On March 10, 2016, the FDA approved Truvada® in the following emtricitabine/tenofovir disoproxil fumarate dosage strengths for the treatment of HIV-1 infection in pediatric patients: 167mg/250mg, 133mg/200mg, and 100mg/150mg ("low dosage strengths").

23. United States Patent No. 6,642,245 ("the '245 Patent," copy attached as Exhibit A), entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2003. The '245 Patent claims, *inter alia*, methods for treating HIV infection in humans with emtricitabine (one of the active ingredients in Truvada®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Truvada®.

24. United States Patent No. 6,703,396 ("the '396 Patent," copy attached as Exhibit B), entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers," was duly and legally issued by the United States Patent and Trademark Office on March 9, 2004. The '396 Patent claims, *inter alia*, emtricitabine (one of the active ingredients in Truvada®), and is listed in the FDA Orange Book for Truvada®.

25. Emtricitabine is a compound that has a molecular formula of $C_8H_{10}FN_3O_3S$, and which has the following chemical structure:




26. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Emtriva® label is "5-fluoro-1-[(2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine." Two chemical names recited for emtricitabine in the '245 Patent are "(–)-β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane" and "β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane." Two chemical names recited for emtricitabine in the '396 Patent are "(–)-cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one" and "(–)-enantiomer of cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one."

27. The named inventors on the '245 and '396 Patents are Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi.

28. Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi assigned the '245 and '396 Patents to Emory.

29. Pursuant to an agreement entered into between Gilead and Emory, Gilead has substantial rights in the '245 and '396 Patents, including, but not limited to, rights associated with being a licensee of the '245 and '396 Patents, and the right to sue for infringement of the '245 and '396 Patents.

**COUNT 1**
**Infringement of U.S. Patent No. 6,642,245**

30. Plaintiffs repeat and reallege paragraphs 1-29 above as if set forth herein.

31. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate (i.e., 100mg/150mg, 133mg/200mg, and 167mg/250mg) for the purpose of treating HIV infection.

32. By letter dated April 5, 2018 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "April 5, 2018 Notice Letter"), Aurobindo USA notified Plaintiffs that it had submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the '245 Patent.[1] This complaint has been filed within 45 days of Plaintiffs' receipt of the April 5, 2018 Notice Letter.

33. In its April 5, 2018 Notice Letter, Aurobindo USA notified Plaintiffs that, as a part of ANDA No. 21-1640, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '245 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '245 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ."

34. Aurobindo USA alleged in its amended May 9, 2018 Notice Letter that claims 1-8 and 15 of the '245 Patent are invalid and that claims 4, 5, and 9-22 would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 21-1640.

35. The May 9, 2018 Notice Letter does not allege non-infringement of claims 1-3 and 6-8 of the '245 Patent.

[1] Aurobindo amended its Paragraph IV Notice Letter on May 9, 2018.

36. By filing ANDA 21-1640 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate before the '245 Patent's expiration, Aurobindo has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

37. Aurobindo's submission of ANDA No. 21-1640 and service of the April 5, 2018 Notice Letter indicates a refusal to change its current course of action.

38. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, will infringe one or more claims of the '245 Patent.

39. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 1 of the '245 Patent. Claim 1 recites a "method for treating HIV infection in humans comprising administering an effective amount of [emtricitabine], or its physiologically acceptable salt, optionally in a pharmaceutically acceptable carrier." On information and belief, Aurobindo will infringe Claim 1 of the '245 Patent because the product for which it seeks approval in ANDA No. 21-1640 will be labeled for and used to treat HIV infection in humans with an effective amount of emtricitabine. For the same reasons, on information and belief, Aurobindo will likewise infringe Claims 2, 4, 6, 7 and 8 of the '245 Patent.

40. On information and belief, the tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, will be administered to human patients in an effective amount for treating HIV infection. Such administration will infringe at least one claim of the '245 Patent,

as described in the preceding paragraph. On information and belief, this administration will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '245 Patent. Further, by filing ANDA No. 21-1640 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '245 Patent.

**COUNT 2**
**Infringement of U.S. Patent No. 6,703,396**

41. Plaintiffs repeat and reallege paragraphs 1-29 above as if set forth herein.

42. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate (i.e., 100mg/150mg, 133mg/200mg, and 167mg/250mg) for the purpose of treating HIV infection.

43. In its April 5, 2018 Notice Letter, Aurobindo USA notified Plaintiffs that it had submitted ANDA No. 21-1640 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate prior to the expiration of the '396 Patent.[2] This complaint has been filed within 45 days of Plaintiffs' receipt of the April 5, 2018 Notice Letter.

44. In its April 5, 2018 Notice Letter, Aurobindo USA notified Plaintiffs that, as a part of its ANDA No. 21-1640, it had filed a Paragraph IV certification with respect to the '396 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '396 Patent, "is invalid or will not be

[2] Aurobindo amended its Paragraph IV Notice Letter on May 9, 2018.

infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ."

45. Aurobindo USA alleged in its amended May 9, 2018 Notice Letter that claims 1-7, 11, 13, 15, and 17 of the '396 Patent are invalid and that claims 8-10, 12, 14, 16, and 18-28 would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 21-1640.

46. The May 9, 2018 Notice Letter does not allege non-infringement of claims 1-7, 11, 13, 15 and 17 of the '396 Patent.

47. By filing ANDA No. 21-1640 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate before the '396 Patent's expiration, Aurobindo has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

48. Aurobindo's submission of ANDA No. 21-1640 and service of the April 5, 2018 Notice Letter indicates a refusal to change its current course of action.

49. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, will infringe one or more claims of the '396 Patent.

50. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 2 of the '396 Patent. Claim 2 recites "[emtricitabine] or a pharmaceutically acceptable salt, ester or salt of an ester thereof." On information and belief, Aurobindo will infringe Claim 2 of the '396 Patent because the product for which it seeks approval in ANDA No. 21-1640 will contain

emtricitabine as the active ingredient. For the same reasons, on information and belief, Aurobindo will also infringe Claims 1, 3-7, 13, 15 and 16 of the '396 Patent.

51. On information and belief, the tablets containing low dosage strengths of emtricitabine/tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No. 21-1640, if approved, will infringe at least one claim of the '396 Patent, as described in the preceding paragraph. On information and belief, the manufacture of these tablets will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet the manufacture of these tablets with knowledge that it is in contravention of Plaintiffs' rights under the '396 Patent. Further, by filing ANDA No. 21-1640 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '396 Patent.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Aurobindo's ANDA No. 21-1640 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '245 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(b) A judgment declaring that the effective date of any approval of Aurobindo's ANDA No. 21-1640 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '396 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(c) A judgment declaring that the '245 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;

(d) A judgment declaring that the ’396 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;

(e) A permanent injunction against any infringement of the ’245 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(f) A permanent injunction against any infringement of the ’396 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(g) To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the ’245 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(h) To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the ’396 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(i) Costs and expenses in this action; and

(j) Such other relief as this Court may deem proper.

Dated: May 18, 2018

Respectfully submitted,

FARNAN LLP

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